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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/689,199

10/20/2003

George P. Teitelbaum

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46333 7590 10/10/2008
HAYNES AND BOONE, LLP
901 Main Street
Suite 3100
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EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

10/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/689,199	Applicant(s) TEITELBAUM ET AL.	
	Examiner JAMES L. SWIGER III	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-30 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-30 and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/20/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sava (US Patent 5,658, 286) and Gelbard (US Patent 5,397,363).

Sava discloses a spinal fixation device comprising first and second bone anchors (14, and see Fig. 2B) each having a proximal and distal (tapered end towards bone) ends. The head of the bone screws also have a portal extending therethrough (the U-shaped portal at the proximal end). Sava also discloses a cross bar (18) that connects a first support structure to a second support structure (see construct in Fig. 2B), and wherein the structure is considered subcutaneous, as it is implantable during the surgery. The cross bar also contains a media that is hardenable (28, and shown 34), and wherein the hardenable media may be made of various polymers as known in the art (see Col. 1) and also disclosed in the art (See Col. 6, lines 52-67).

Sava discloses the claimed invention except for a support structure that connects a first and second bone anchors and cross ties to connect the supports. Gelbard discloses support structures (36) that are able to connect the bone anchor portals (the

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punctured holes fit into the portal of the proximal end of the bone anchors) and a cross bar (see also Col. 4, lines 18-36). Gelbard also discloses what may be considered cross ties (37), as they are also able to help fix a rod into position (Col. 4, lines 37-55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spinal device of Sava having at least the support structure and cross ties of Gelbard to better secure and lock the device in use.

Claims 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sava '286 and Gelbard '363 as applied to claim 26 above, and further in view of Burton (US Patent 4,743,260). The combination of Sava '286 and Gelbard '363 disclose the claimed invention except for more specifically, a cross bar with apertures. Burton discloses holes in the cross bar (19) that are adapted to aid the cross bar to connect to the bone anchor. Burton further discloses multiple fibers that act as reinforcement (See Col. 4, lines 15-53). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Sava '286 and Gelbard '363 having at least a cross bar with apertures in view of Burton to better secure the spinal device in use.

Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over combination of Sava '286 and Gelbard '363 as applied to claim 26 above, and further in view of Stalcup et al. (US Patent 6,336,930). The combination of Sava '286 and Gelbard '363 disclose the claimed invention except for a support structure having hardenable media. Stalcup et al. discloses a plate structure which is also considered at least a support structure. Stalcup et al. further disclose this plate/support having a

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polymer bag which, when filled and hardened, provides further support to the plate portion (see Col. 1, lines 34-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Sava '286 and Gelbard '363 having at least a support structure with hardenable material in view of Stalcup et al. to better secure and orient the device as needed.

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sava and Gelbard as applied to claim 26 above, and further in view of Carl et al. (US Patent 6,607,530). The combination of Sava and Gelbard disclose the claimed invention except for a hardenable material specifically comprising an epoxy or polyurethane. Carl et al. disclose an orthopedic construct that utilizes hardenable material such as an epoxy (Col. 11, lines 35-45) or polyurethane (Col. 8, lines 55-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Sava and Gelbard having at least materials made from epoxy or polyurethane as taught by Carl et al. that, though known in the art based on their suitability for forming a support structure, would allow for improved precision and placement of a tube or support structure in the surgical application.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sava and Gelbard as applied to claim 26 above, and further in view of Holmes (US Patent 5,415,661). Sava and Gelbard disclose the claimed invention except for reinforcing fibers placed in the cross bar cavity. Holmes discloses an implantable construct that has reinforcing fibers (Col. 6, lines 23-34), which allow for optimal levels of reinforcement after settlement and formation in the spinal area after

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surgery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the above combination having at least reinforcing fibers as taught by Holmes to have a stronger, implantable fixation device after it is properly formed during the surgical procedure.

Finality

The finality of the previous office action dated 4/30/2008 is hereby withdrawn due to omitted claims 33 and 34. Rejections are found above.

Response to Arguments

Applicant's arguments filed 6/30/2008 have been fully considered but they are not persuasive. It is held that the prior art still reads on the claimed invention. It is noted that the cross bar of Sava shown as 18 connects to the support structures. Claim 1 claims "a cross bar, which connects the first support structure to the second support structure to form an orthopaedic construct." The support structures, as noted in the response, are item 36 in Gelbard. As shown in Gelbard, at least a portion of the support structures extend through and connect to the heads and portals of the bone anchor. The cross bars cross through the portal as well, and thus, the cross bar, having the media connects the support structures.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER III whose telephone number is

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(571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/
Examiner, Art Unit 3775

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733